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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,715	03/04/2005	Stefan Golz	Le A 35 949	3124

35969 7590 07/27/2007

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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,715	GOLZ ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims:

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 May 2007 has been entered.

Amendments and remarks filed with RCE request have been entered. Claims 1-3 have been amended and the amendments made of record. Claims 1-11 are currently under consideration.

Information Disclosure Statement:

The Information Disclosure statements (IDS) submitted on the 10 May 2007, has been considered. Signed copy is attached.

New/Maintained Rejections

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis for the recitation of "said test compound" in section i) of claim 2.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claim recites : i) determining the activity of a FPRL1 polypeptide at a certain concentration of a test compound; ii) determining the activity of a FPRL-1 polypeptide in the presence of a regulator of a FPRL-1 polypeptide; and iii) identifying the test compound as a potential therapeutic agent if activity of the FPRL-1 polypeptide is inhibited in the presence of the test compound and the compound known to be a regulator. The omitted steps are: a step that recites determining the activity of the FPRL-1 polypeptide in the presence of both the test compound and the regulator. It is unclear how one could determine if the activity of the FPRL-1 polypeptide is inhibited in the presence of the test compound and the compound known to be a regulator, if there is no step reciting contacting the FPRL-1 with the test compound in the presence of a regulator.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record and reasons set forth below.

Applicant traverses this rejection. The reasons for the traversal are:

a. In response of 4 March 2007, applicant asserts that FPRL1 is highly expressed in cardiovascular tissues, which indicates an association between FPRL1 and cardiovascular disease.

b. In response of 10 May 2007, applicant has submitted post-filing date art, which applicant asserts support the specification's disclosure that the FPRL1 ligand

lipoxin A4 is involved in cardiovascular diseases, respiratory diseases, and genitor-urological disorders.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons.

In response to a: Table 1 presents data of mRNA expression (relative expression) in various tissues. While expression in heart ventricle is 2048, this is much lower than expression in other tissues, such as esophagus (13216), which is not a cardiovascular related tissue. Since the relative expression of mRNA is much greater in non-cardiovascular tissues such as leukocytes, esophagus, liver, and placenta than it is in the first named cardiovascular tissue (hear ventricle (left)), one would be unable to predict a specific association between FPRL1 polypeptide and cardiovascular disease. Additionally, the presented data comprises difficult to interpret results, as the relative expression of mRNA encoding FPRL1 polypeptide in cardiovascular related tissue ranges widely, from 241 in sample identified as "heart" to 2048 in sample identified as "heart ventricle (left)". Therefore, one could conclude that the level of expression of mRNA in cardiovascular tissue is low, and would not predict an association between FPRL1 polypeptide and cardiovascular disease.

In response to b: Applicant has submitted three post filing date references; these references teach that ligands of the FPRL1 receptor (also known as the ALX receptor), lipoxin A4, display potent anti-inflammatory properties, and would thus have therapeutic potential. However, the post-filing date evidence does not compensate for the lack guidance in the specification as to whether one is screening for an agent that agonizes or antagonizes the FPRL1 receptor.

The specification teaches: The invention provides methods for identifying compounds which can be used for the treatment of hematological and cardiovascular diseases, disorders of the peripheral and central nervous system, COPD, asthma, genito-urological disorders and inflammation diseases. The methods entail the identification of candidate or test compounds or agents which bind to FPRL1 and/or

have a stimulatory or inhibitory effect on the biological activity of FPRL1 [paragraph 0167 of PGPUB 20050164305, the PGPUB of the instant invention].

The references submitted by applicant all teach that activation of the ALX receptor generate signaling events that result in anti-inflammatory effects.

One would therefore predict that a therapeutic agent would need to be an activator of FPRL1 receptor, not an inhibitor of FPRL1 activation. It would require undue experimentation to determine how one would use the claimed methods to screen for a therapeutic agent if one does not know to screen for activators or inhibitors of biological activity of FPRL1

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1, 2, 4, 5 and 10 under 35 U.S.C. § 102(b) as being anticipated by Gronert et al (1998, J Exp Med. 187:1285-1294) is maintained for reasons of record and for reasons set forth below. In the advisory action of 15 March 2007, the Examiner indicated that this rejection has been overcome. However, upon further consideration, the rejection has been reinstated.

Applicant traverses this rejection (Remarks of 4 March 2007). The reason for the traversal is that Gronert does not disclose any of the recited disorders, including the elected species of cardiovascular diseases.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons.

Applicant has not provided evidence of a nexus between changes in FPRL1 structure, expression or activity and any disease condition and therefore has not provided an enabling disclosure. Furthermore, Gronert et al. teach that LXA4 directly

modulates the initiation of inflammatory events by inhibiting the release of the potent chemokine IL-8 (page 1293, 2nd column, 1st paragraph); thus, LXA4 stable analogs have potential therapeutic benefits (abstract). Therefore, only the actual method steps are considered and the teachings of Gronert et al anticipate the limitations of claims 1, 2, 4, 5 and 10.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of Claims 1-6, 8-10 under 35 U.S.C. 103(a) as being unpatentable over Gronert et al in view of Fiore et al (1994, J Exp Med. 180:253-260) is maintained for reasons of record and for reasons set forth below.

The rejection of Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Gronert as applied to claim 1 in view of Ramakrishnan (US PGPub 2002/0058259, filed 14 March 2001) is maintained for reasons of record and for reasons set forth below.

The rejection of Claims 1 and 11 under 35 U.S.C. 103(a) as being unpatentable over Gronert et al in view of Seo et al (1997, J Immunology 158:1895-1901) is maintained for reasons of record and for reasons set forth below.

In the advisory action of 15 March 2007, the Examiner indicated that this rejection has been overcome. However, upon further consideration, the rejection has been reinstated.

Applicant traverses these rejections (Remarks of 4 March 2007). The reason for the traversal is that there is no prima facie case of obviousness because Gronert et al does not disclose a connection between recited polypeptide and any of the diseases

recited in the claims of the instant invention and none of the secondary references remedies this deficiency.

Applicant's arguments have been fully considered but are not found to be persuasive for reasons of record and reasons outlined above.

Conclusion:

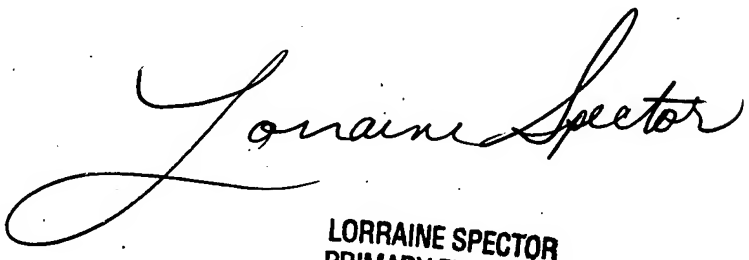
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHS



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PRIMARY EXAMINER